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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,888	02/04/2004	James M. Brugger	53951-118	5367

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PROSKAUER ROSE LLP  
PATENT DEPARTMENT  
1585 BROADWAY  
NEW YORK, NY 10036-8299

EXAMINER
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KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/772,888

Applicant(s)

BRUGGER ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 16, 18, 19, 21 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 15, 17, 20 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/12/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Claims 14, 19 and 24 are objected to because of the following informalities: On line 3 of each of claims 14, 19 and 24, “and” should be inserted between “a blood circuit portion” and “a non-blood circuit portion”. Appropriate correction is required.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14, 18 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Twardowski (US Patent No. 5,484,397). Regarding claim 14, Twardowski teaches a fluid processing apparatus comprising an extracorporeal blood treatment fluid circuit including a blood filter (100) e.g. hemodialyzer and having a blood circuit portion (146) and a non-blood circuit portion (94) separated by a membrane of the blood filter, a double lumen catheter having lumen (145a) and (145b) connected to an inflow (144) and an outflow line (146) of blood circuit portion wherein lumens are releasably connected to the blood circuit portion (see Fig. 2; col. 10, line 63 – col. 11, line 22; col. 13, lines 22-67). Catheter inherently has a spike.

Regarding claims 18 and 23, Twardowski teaches the blood filter (100) having two openings for a blood inlet and a blood outlet and connected to the lumens (145a, 145b) (see Fig. 2).

Regarding claim 24, Twardowski teaches a fluid processing apparatus comprising an extracorporeal blood treatment fluid circuit including a blood filter (100) e.g. hemodialyzer and having a blood circuit portion (146) and a non-blood circuit portion (94) separated by a membrane of the blood filter, a double lumen catheter having lumen (145a) and (145b)

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connected to an inflow (144) and an outflow line (146) of blood circuit portion wherein lumens are releasably connected to two openings of the blood filter (100) and a sterile container (164) is connected to the blood circuit portion (146) via a connector (166) (see Fig. 2; col. 10, line 63 – col. 11, line 22; col. 13, lines 22-67).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Twardowski in view of Utterberg et al '624 (US Patent No. 5,772,624). Twardowski teaches a fluid processing apparatus as described in above paragraph 3. Claim 19 essentially differs from the apparatus of Twardowski in reciting that a second lumen having a lumen connector and the blood circuit portion having a circuit connector to mate with the lumen connector. Utterberg et al '624 teaches a fluid processing apparatus comprising a blood tube (72) having a luer lock type connector (76) mating with needle having a tube connector (198) for aseptic connection (see Fig.

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11; col. 8, lines 39-41; col. 14, lines 4-7). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Twardowski to provide a lumen with a lumen connector and the blood circuit portion with a circuit connector for facilitating aseptic connection of the lumen and the blood circuit portion.

6. Claims 16, 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Twardowski as applied to claims 14 and 24 above, and further in view of Mahurkar (US Patent No. 4,134,402). Twardowski teaches a fluid processing apparatus as described in above paragraph 3. Claims 16, 21 and 25 essentially differ from the apparatus of Twardowski in reciting that one of the two lumens opens at the distal end further from the base than the other lumen opens at the distal end. Mahurkar teaches a double lumen hemodialysis catheter comprising one of the two lumens opens at the distal end further from the base than the other lumen opens at the distal end to prevent mixing of the blood during the hemodialysis operations (see Figs. 1, 4; col. 2, lines 19-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the double lumen catheter of Twardowski to have one of the two lumens opens at the distal end further from the base than the other lumen opens at the distal end to prevent mixing of the blood during the hemodialysis operations as suggested by Mahurkar (see col. 2, lines 23-26).

7. Claims 15-17 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 20-22 respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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8. Claims 15, 17, 20 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The declaration under 37 CFR 1.132 filed 7/12/06 is insufficient to overcome the rejection of claims 1-4, 6 and 8-12 based upon Brugger et al (US Patent No. 6,649,063) as set forth in the last Office action because: the declaration should be filed under 37 CFR 1.131 showing the derivation, see MPEP 715.01 (c), II.

10. Applicant's arguments with respect to claims 14-25 have been considered but are moot in view of the new ground(s) of rejection.

Twadowski in view of Utterberg et al '624 or Mahurkar teaches new claims 14, 16, 18-19, 21 and 23-25.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

JK  
September 21, 2006